

REMARKS

The amendment to the specification to the three paragraphs at page 15, deleting the adjective “paste” from modifying “composition” is to conform the relevant portion of the specification with the comments of the Patent Office. The amendments to the specification at page 5, line 27, merely add the full name to the well known acronyms TGF-beta (“tissue growth factor-beta”) and PDGF (“platelet derived growth factor”). The amendment to the specification at page 15, line 14, does not add new matter. Rather, it incorporates the phrase “or combinations thereof” from originally filed claim 11, which recites the identical phrase “or combinations thereof” in the context of the three recited exothermic salts (“11. The paste composition of claim 10, wherein said exothermic salt comprises Magnesium chloride, Sodium sulfate, or Magnesium sulfate or other exothermic salts, **or combinations thereof.**”) The case law permits an inventor to amend the specification to include text from an originally filed claim. *See* For all these reasons, the amendment to the specification does not add new matter.

The amendments to the claims also do not add new matter. The claims have been amended to delete reference to the preambular terms “paste,” “dried” and “reconstituted” which gave rise to the rejection under § 112 and which are not given any weight anyway. Claim 1 has been amended to incorporate the text from dependent claims 10 and 11 which recite the various exothermic salts and combinations thereof. Claim 1 has also been amended to recite the full text “demineralized bone matrix” for the acronym “DBM” as used therein. Support for this term is found in the specification at page 5, lines 8-9 (“Demineralized Bone Matrix (DBM).”)

Independent claim 12 has been amended to parallel claim 1 except that the transition term in claim 12 is “consisting essentially of,” whereas in claim 1, the transition term is “comprising.”

Independent claim 19 has been amended to parallel claim 1 except that the claim recites that the composition comprising the mixture of recited components is “lyophilized.” Support for the mixture being “lyophilized” (*i.e.*, freeze dried) is found in the specification at page 3, lines 4-5 (“In contrast, the subject invention allows the graft paste to

be processed down to its critical components, for example, **by freeze-drying. . .**"); at page 3, lines 10-11 ("The subject invention also pertains to **freeze-dried compositions** that possess osteogenic, chondrogenic or chondroprotective, or other beneficial properties."); and at page 9, line 18 ("Upon **lyophilization** of the contents of the syringe 10, . . .").

New claims 21-27, which depend from claim 19, parallel the existing dependent claims and are supported in the specification at Example 2, and more specifically at page 15, lines 1-18.

For all these reasons, the amendments to the claims do not add new matter.

BASES FOR OBJECTION/REJECTION

Claims 1-20 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Claims 13-14 and 16-20 are rejected under 35 U.S.C. §§ 102(a) and (e) for allegedly being anticipated by commonly assigned U.S. published Application 2001 0018614 (Bianchi).

Claims 1, 5 and 18-20 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,472,840 (Jefferies).

Claims 1, 5 and 18-20 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,804,744 (Sen).

Claims 1-20 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,707,962 (Chen), in view of U.S. published Application 2001 0018614 (Bianchi), U.S. Pat. 5,405,390 (O'Leary); and U.S. Pat. 6,679,918 (Benedict).

The Applicants will address each of these bases for rejection in Sections I-V, respectively, which follow.

I. 35 U.S.C. § 112, Second Paragraph

Claims 1-20 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Patent Office, the terms "paste," "dried" and

“reconstituted” render the claims indefinite. In particular, the Patent Office contends that “[i]t is unclear what percentage water is allowed in a paste or a dried paste or what percentage water is necessary to be considered reconstituted.” [Official Action at page 2.] In response, the Applicants have amended the claims to delete reference to “paste” or “dried paste” and “reconstituted.” Accordingly, this basis for rejection has been rendered moot.

Separately, the Patent Office stated that the first use in the claims of the acronym “DBM” should be defined. In response, the Applicants amended claim 1 to recite that DBM is “demineralized bone matrix.” Accordingly, this basis for rejection has been rendered moot.

II. 35 U.S.C. §§ 102(a) and (e) over U.S. Pub App. No. 2001 0018614 (Bianchi)

Claims 13-14 and 16-20 are rejected under 35 U.S.C. §§ 102(a) and (e) for allegedly being anticipated by commonly assigned U.S. Published Application 2001 0018614 (Bianchi). Claim 20 has been cancelled. Accordingly, only claims 13-14 and 16-19 are at issue. Each of claims 13-14 and 16-19 now includes as an element “an exothermic salt that heats upon contact with a reconstitution fluid.” Bianchi does not teach or suggest a composition having an “exothermic” salt nor any of the salts specifically itemized in the specification. For these reasons, claims 13-14 and 16-19 would not have been anticipated by Bianchi.

III. 35 U.S.C. § 102(b) and (e) over U.S. Pat. 4,472,840 (Jefferies)

Claims 1, 5 and 18-20 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,472,840 (Jefferies). Claim 20 has been cancelled. Accordingly, only claims 1, 5 and 18-19 are at issue. Each of claims 1, 5 and 18-19 now includes as an element “an exothermic salt that heats upon contact with a reconstitution fluid.” Jefferies fails to teach or suggest a composition having an “exothermic” salt nor any of the salts specifically itemized in the specification. For these reasons, claims 1, 5 and 18-19 would not have been anticipated by Jefferies.

IV. 35 U.S.C. § 102(b) and (e) over U.S. Pat. 4,804,744 (Sen)

Claims 1, 5 and 18-20 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,804,744 (Sen). Claim 20 has been cancelled. Accordingly, only claims 1, 5 and 18-19 are at issue. Each of claims 1, 5 and 18-19 now includes as an element “an exothermic salt that heats upon contact with a reconstitution fluid.” Sen fails to teach or suggest a composition having an “exothermic” salt nor any of the salts specifically itemized in the specification. For these reasons, claims 1, 5 and 18-19 would not have been anticipated by Sen.

V. 35 U.S.C. § 103(a) over Chen, Bianchi, O’Leary and Benedict

Claims 1-20 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,707,962 (Chen) or U.S. Pat. 6,180,605, in view of U.S. published Application 2001 0018614 (Bianchi), U.S. Pat. 5,405,390 (O’Leary), and U.S. Pat. 6,679,918 (Benedict). Claim 20 has been cancelled. Accordingly, only claims 1-19 are at issue. Each of claims 1-19 now includes as an element “an exothermic salt that heats upon contact with a reconstitution fluid.” The cited art, alone or in combination, does not teach or suggest a composition having an “exothermic” salt nor any of the salts specifically itemized in the specification. For these reasons, claims 1-19 would not have been unpatentable over U.S. Pat. 5,707,962 (Chen) or U.S. Pat. 6,180,605, in view of U.S. published Application 2001 0018614 (Bianchi), U.S. Pat. 5,405,390 (O’Leary) and U.S. Pat. 6,679,918 (Benedict).

SUMMARY

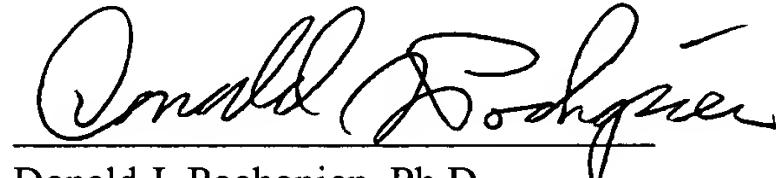
Claims 1-20 have been rejected. Claim 20 has been cancelled. Claims 21-27 have been added by amendment herein. Accordingly, claims 1-19 and 21-27 are pending.

In view of the amendments herein, all bases for rejection of claims 1-19 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite has been rendered moot. In view of the amendments herein, adding the element “an exothermic salt that heats upon contact with a reconstitution fluid,” all bases for rejection for anticipation or obviousness have been rendered moot. None of the cited references, alone or in combination, teaches or suggests this element. Moreover, each of new claims 21-27 includes this element. Hence, the prior bases for rejection would not be applicable to new claims 21-27. For all these reasons, claims 1-19 and 21-27 are in condition for allowance

Respectfully submitted,

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